EXHIBIT F

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Institute of Microbiology, Infectious and Epidemic Diseases of the Veterinary Faculty of the Ludwig-Maximilian University of Munich (Director: Prof. Dr. Oskar-Rüger Kaaden)

History of Variola, Smallpox Eradication and MVA

Anton Mayr

1. History of Variola

Smallpox (variola, petite vérole, viruela, vajuola) is an extremely old, very distinct **generalised exanthematous viral disease.** It afflicted humanity all over the world at regular intervals and with similar severity from ancient times until well into to modern times. The deadly nature of this scourge has therefore imprinted itself deeply on people's minds, as a smallpox epidemic generally reduced the size of an unprotected population by more than one third. The survivors were left with pockmarks for the rest of their lives (4).

The beginnings of the disease go back to several thousand years BC, probably to a **primitive Central Asian viral source.** A **goddess of the pox** was mentioned as early as 1500 B.B. in Sanskrit writings in **India**. in 1112 BC the disease was also recorded for the first time In China. There are, however, no reliable records on the occurrence of smallpox in ancient Egypt, Greece or Rome. One very detailed description of smallpox was recorded in about 900 AD by physicians trained in Persia (**Zakarja Razi**). Subsequent smallpox epidemics in Europe, the Americas, Africa and finally, in 1838, in Australia were without doubt the result of voyages, crusades, wars and international trade, above all the slave trade. The Saracens brought smallpox to Spain, for instance, from whence it spread over the whole of western Europe. In 570 AD, smallpox is mentioned in southern France in a report written by Bishop **Marius of Avenches,** in which it is designated as **variola** (derived from "la petite vérole") for the first time. In the Middle Ages and right up to the beginning of the 19th century, devastating epidemics of the disease again and again ravaged Europe at regular intervals. It is estimated that in Germany alone, with its population of approx. 24 million at that time, smallpox claimed the lives of approx. 67,000 people every year.

As recently as 1870-73, at the start of the vaccination era and during the last major pandemic, over 100,000 deaths were recorded in Germany (cf. Table 1).

The source of idiopathic human smallpox is classified as the **Orthopoxvirus (OPV) variolae** species of the orthopoxvirus genus of the **Poxviridae** family.

Pathogenically, smallpox is a generalised, cyclical viral disease involving a number of stages. The following stages are distinguished:
Incubation (12-14 days)
Initial stage (generalization phase): 2-3 days, fever, chills, pain in the neck and back, fatigue, transitory skin symptoms (non-virus-specific symptoms)
Smallpox rash stage (eruptive stage): 4-8 days, development of typical rash on skin and mucous membranes, intermittent papules, vesicles, pustules, pockmarks)
Organic manifestation stage: 8-20 days, generalizing smallpox rash on skin and mucous membranes, fever, myocarditis, swollen lymph nodes, pneumonia, secondary bacterial infections
Healing stage: 3rd to 4th week of illness, scabs formed on pustules, recovery
Sequelae: pneumonia, decubitus, secondary infections.

The cyclical course of the disease may come to a halt at any stage and lead to recovery with pockmarks but also to death. Severe forms of the disease, generally ending in death, are **variola confluens** (rapid progress of the disease, confluent blisters and pustules all over the body), **variola pustula haemorrhagica** (secondary haemorrhagic variola, bleeding into the variola confluens) and **purpura variolosa** (primary haemorrhagic variola, the severest form, subconjunctival, petechial haemorrhaging, death within 24 to 72 hours, generally before the outbreak of a generalizing smallpox rash).

The normal form of the disease, which varies in severity, is designated as **variola major**, an especially mild or abortive form as **variola minor** or **alastrim** (4).
Variola major : typical smallpox, with a case-fatality rate of 20% to 50% in non-vaccinees, depending on age and other environmental and host factors.
Variola minor (alastrim): mild form with a case-fatality rate of less than 5% in non-vaccinees.

In 1980, the WHO declared smallpox to have been eradicated throughout the world. Idiopathic human smallpox, derived from the **variola/alastrim** virus, has so far (1999) not recurred. The unique success of the program for the eradication of such a dangerous disease, posing a threat to the whole of humanity, was only possible because of the seamless **interaction** of rigorously conducted worldwide **vaccinations** combined with **government measures** on the one hand and the **specific features, pathogenesis and immunology** of smallpox on the other (1, 2).

Smallpox vaccination was employed all over the world and was made compulsory in many countries. It was carried out systematically from infancy onwards with repeat vaccination at the age of 10 to 12 years (second vaccination) and stringently monitored in international tourism. A live vaccine from the heterologous vaccinia virus (serologically uniform) was employed uniformly; this virus possesses complete cross-immunity with the variola virus, has reduced virulence for humans after cutaneous application and is only slightly contagious. It multiplies in the vaccinated person and produces complex, long-lasting, cellular and humoral immunity. Within the context of **government measures**, the public-health authorities of the various countries kept one another informed (WHO monitoring program) and issued warning systems and comprehensive quarantine regulations and control strategies (**compulsory notification**). **Epidemiologically speaking**, the variola virus is a **monophagic virus** whose only host, under normal circumstances, was the human being. This being the case, transmission took place via homogeneous, homonous infectious chains (droplet infection). There was no reservoir for the variola virus in the animate or inanimate environment.

After infection with the variola virus, the **pathogenic chain of events** generally led to disease, rarely to subclinical forms thereof. In both cases, a complex, long-lasting, cellular and humoral immunity developed after survival from the infection, which prevented permanent (latent, tolerated, occult) forms. **Immunologically** and serologically, the variola/alistrim virus was uniform. The above conditions were prerequisites for eradication of variola (1, 2).

2. History of Variola Vaccination

The first attempts to protect humans against smallpox go back to the early history of this disease. It is no longer possible to state in which century BC the Chinese began to protect children and smallpox-endangered persons from the disease by putting dried, powdered smallpox scabs in their noses (**Einpropfung, inoculation**), or when the natives of South America used cowpox for this purpose. At any rate, the Chinese and the Indians reported that they introduced smallpox scabs, pustules and pustule contents into the skin of children in order to produce a mild disease which would then provide full protection against this often lethal disease. In the 17th century, this method (which was then called **variolation**) was revived in the Near East and was also brought to Europe. So-called **smallpox centres** arose, their sole purpose being to collect pustule material, above all the contents thereof, from smallpox victims in order to use it for the purpose of variolation. Variolation had a marked effect on the course of smallpox epidemics in Europe. The latter was characterised, on the one hand, by the iatrogenic spread of the variola virus in the form of modified, mild smallpox in inoculated persons and on the other hand, by the spread of naturally acquired smallpox, which was intensified by the growth of the population and trade, with severe forms.

The period of **inoculation (variolation)** came to an end with **Edward Jenner's** experimental development between 1796 and 1798 of a **vaccination** method using an heterologous pox virus of animal origin. He proceeded from the observation made again and again well before then that persons such as farmers, milkmaids and cowshed workers who had been infected with cowpox either accidentally or on purpose were immune to human smallpox. Persons infected with cowpox merely exhibited localised pustules on the skin, which healed quickly without generalised symptoms developing. E. Jenner first inoculated a small boy cutaneously with the contents of a cowpox pustule from the **hand of a milkmaid** and subsequently demonstrated via variolation that the child was immune to smallpox. Two years later (in 1798), he vaccinated a child cutaneously **directly from a cow**, then vaccinated a second child with material from a cowpox pustule on the first child and a further 4 children arm-to-arm. All the children developed localised pox pustules and were immune to subsequent infection with real smallpox (Table 2).

Although modern smallpox vaccination was still a long way off, the vaccine, as a **heterologous live-virus vaccine,** has basically remained unchanged, i.e. it is still derived from cows or a bovine pox virus (infection possibly via other animal pox, e.g. horsepox). The name "vaccine" was given to it (French "vaccin", from Latin ""vacca" = cow) on the basis of its source and the active bovine pox virus it contains was called **vaccinia virus** (1, 2, 4, 12).

The successful advance of vaccination all over the world was unique. The **first vaccination institute** in the world was set up in London in 1799. Germany's **first vaccination law** was adopted in Bavaria in 1807, to be followed by the **Reich Vaccination Act** for the whole of Germany on 8th April 1874 and the founding of **government vaccination institutes** (e.g. Bavaria in 1801, Berlin in 1803, Breslau in 1804). Developments were similar in other countries (primary and re-vaccination), with vaccination being made mandatory by law in some cases.

Smallpox vaccination was generally carried out **cutaneously** (percutaneously, intracutaneously) but the types of vaccine used changed continuously. The most important stages were: 1. **humanised vaccine** (child-child-child), 2. **retrovaccine** (child-rabbit-child or child-cow-child), 3. **bovine or donkey vaccine, 4. egg vaccine**, and 5. **cell culture vaccine**. In all cases, a live-virus vaccine was involved, which was constantly improved with respect to the type of vaccinia virus (most recently the Elstree virus strain recommended by the WHO), proliferation system, virus titre and purity. Vaccine derived from cows was used for the longest period (propagation of the virus on the scarified skin of live calves). The egg and cell-culture vaccines were developed just before smallpox was eradicated and were never used officially (1, 4, 6, 8).

The following definitions were commonly used when reference was made to the execution and assessment of smallpox vaccination:
Vaccination: cutaneous immunization with smallpox vaccine of a person previously not immunised successfully (synonym: **initial vaccination**).
Revaccination: cutaneous immunization with smallpox vaccine of a person with a vaccination scar or in possession of well substantiated proof of prior, successful vaccination or revaccination.

Repeat vaccination or repeat revaccination: renewed vaccination of a person in whom vaccination or revaccination has failed to elicit an unequivocal reaction.

Successful vaccination or revaccination: occurrence of an unequivocal reaction after vaccination or revaccination (synonym: **effective vaccination**).

Major reaction:

1. presence of a typical Jennerian vesicle at the follow-up examination one week after primary vaccination.
   presence of a vesicle or pustule or a clearly palpable hardening or congestion around a central lesion, which may be a scab or ulcer and is detected 6 to 8 days after **repeat vaccination**.

Equivocal reaction: any vaccination or revaccination reaction that differs from an unequivocal one.

Postvaccinal complications, above all postvaccinal encephalitis, have stimulated all kinds of research (11). **Vaccines made from inactivated vaccinia** virus did not provide lasting protection; the **vaccine antigen** as per **Herrlich** (4) proved its worth as a preliminary vaccine in some cases where vaccination posed a risk, but the **MVA vaccinia virus**, attenuated via numerous cell cultures, was the first vaccine to make risk-free **parenteral vaccination** possible (Table 3).

3. History of MVA

Apart from unhygienic cutaneous application, one of the major problems faced by smallpox vaccination from the very outset was that of **postvaccinal complications** (e.g. localised reactions, eczema vaccinatum, vaccinia secundaria, vaccinia generalisata), above all postvaccinal encephalitis (PvE) with permanent damage and deaths. The latter complication occurred above all in children aged 3 years or more after initial vaccination. Depending on the country concerned, the incidence of PvE in persons vaccinated for the first time varied from country to country and ranged from 1:5000 to 1:100,000. Revaccination in successfully vaccinated persons, on the other hand, was almost never burdened by the problem of PvE. **Cutaneous vaccination** also allowed dermal organisms and spores to enter together with the vaccine, causing dangerous diseases such as tetanus.

In order to **reduce** or completely **prevent** the complications associated with vaccination and to make harm-free parenteral vaccination possible, numerous attempts were made to **inactivate** or **attenuate** the vaccinia virus strains used for the vaccine. Inactivation of the virus, no matter what method was employed, was out of the question, because loss of reproductive ability of the virus also meant loss of its specifically immunizing efficacy. The attenuation methods known at that time, *viz.* through continuous passages in various host systems, above all cell cultures, had the disadvantage either of complete loss of virulence or insufficient attenuation of virulence and/or retention of postvaccinal complications (5).

In the period from 1960 to 1974, the author (**A. Mayr**) succeeded in attenuating the dermal vaccinia strain **Ankara (CVA)** through 572 continuous passages in primary chicken embryo fibroblast cultures (CEF) from Valo eggs in such a way that the above-mentioned disadvantages (postvaccinal complications, cutaneous application) no longer applied. After selection and cloning via plaque passages and clinical testing in humans and animals, it received the name **MVA = modified vaccinia virus**, in order to exclude the possibility of confusion with other attenuated strains. It retained its original immunogenicity and its protective effect against variola and general orthopox infections and offers a greatly diminished virulence for humans and animals combined with the loss of contagiousness. Vaccination-induced disease does not even occur in newborn animals (mice, rabbits, chickens) and immunosuppressed vaccinees (radiation, iatrogenic immune suppression). Local (cutaneous, oral, intranasal) and parenteral (subcutaneous, intramuscular, intraperitoneal) administration of MVA are both possible and involve no risk or loss of immunising efficacy (9, 10).

The fact that MVA offers the possibility of parenteral active immunisation against orthopox without loss of efficacy or the risk of postvaccinal complications opened up completely new avenues for pox prevention in humans and animals. Care must be taken in connection with the use of the MVA strain, whose virulence is greatly diminished, as its protective effect will only be ensured if the vaccine contains sufficient virus (> $10^{7.0}$ KID_{50}) and revaccination takes place after 3 - 5 weeks.

In Germany, the MVA strain was officially authorised for two-stage parenteral smallpox vaccination in children in 1976. Until compulsory smallpox vaccination was abolished, approx. 150,000 initial vaccinations, including vaccinations of children with a vaccination risk, were carried out subcutaneously using MVA without any postvaccinal complications.

After variola had been declared eradicated by the WHO in 1980, the live-virus vaccine MVA was increasingly used for vaccination against **a growing number of orthopox infections in various animal species** that were becoming dangerous for humans, too, as a result of the absence of or decline in vaccine-induced immunity in the population (e.g. catpox); it received official authorization from the competent authorities for this purpose (e.g. in mice breeding, dogs, cats, horses, cattle, elephants and other zoo animals). Since then, the demand for MVA vaccine, which can be used parenterally and without risk on susceptible animals and at-risk groups of persons (e.g. in pox laboratories), has grown (7).

Apart from its use as a vaccine, MVA has, in recent years, proved its worth worldwide as an especially suitable **vector for insertion** of genes coded for foreign protein because of its deletions, its strongly diminished virulence and abortive reproduction in humans and animals. MVA is thus used for producing **vector vaccines** and as a mediator of other **biologically active proteins**. A brief summary of the evolution of MVA is given in Table 4 (13).

Abstract

After the WHO had declared smallpox to be eradicated in 1980, smallpox vaccination ceased to be carried out in humans all over the world. The cutaneous inoculations carried out with live vaccines based on the vaccinia virus from 1798 onwards protected both the global population and, indirectly, the animals living with humans against orthopox infections in general. A large percentage of humans and animals no longer enjoy this protection. Idiopathic orthopox in animals (reservoir possibly rats and mice) are thus experiencing a renaissance, posing a threat to humans and animals.

The author, as a witness of our times, provides an historical retrospective of smallpox epidemics in humankind, their course of development and methods employed to combat this disease, commencing long before the birth of Christ with primitive attempts in China and India and from the end of the 18th century with increasingly enhanced methods, most recently with worldwide smallpox vaccination programmes using live vaccinia vaccines. Smallpox vaccination was always accompanied by a variety of complications, especially postvaccinal encephalitis. The MVA strain was developed to reduce or prevent such adverse effects.

MVA has meanwhile proved its worth both as a parenteral vaccine against orthopox infections in humans and animals and as a vector for insertion of foreign genes.

The history of smallpox, the fight against this disease and the development of MVA are documented with the help of figures and tables.

Reference:

1. Baxby, D. (1999): Eduard Jenner's inquiry; a bicentenary analysis. Vaccine **17**, 301-307.

2. Fenner, F. (1977): The eradication of small pox. Progr.med.Virol. **23**, 1-13.

3. Herrlich, A. (1959): Über Vakzine-Antigen. Münch.Med.Wschr. **101**, 12-14.

4. Herrlich, A. (1967): Die Pocken. 2.Auflage. G.Thieme Verlag, Stuttgart.

5. Herrlich, A. und A.Mayr (1954): Vergleichende experimentelle Arbeiten über die „Vaccine-Kuhpocken-Viren". Arch.Hyg. **138**, 479-504.

6. Herrlich, A. und A.Mayr (1957): Pockenimpfstoff aus Zungengewebekulturen vom Rind. Zugleich ein Beitrag zum Problem der Kulturvaccinen. Arch.Virusforsch. **7**, 284-291.

7. Mahnel, H. und A.Mayr (1994): Erfahrungen bei der Schutzimpfung gegen die Orthopocken von Mensch und Tier mit dem Impfstamm MVA. Berl.Münch.Tierärztl.Wschr. **107**, 253-256.

8. Mayr, A. (1953): Die Herstellung einer primär bakterienarmen bzw. bakterienfreien Pockendermovaccine. Arch.Hyg. **138**, 302-313.

9. Mayr, A. und E.Munz (1964): Veränderungen von Vacciniavirus durch Dauerpassagen in Hühnerembryofibroblasten-Kulturen. Zbl.Bakt.Hyg.I.Abt.Orig. **195**, 25-34.

10. Mayr, A., H.Stickl, H.K.Müller, K.Danner und H.Singer (1978):
Der Pockenimpfstamm MVA.
Zbl.Bakt.Hyg.I.Abt.Orig.B **167**, 375-390.

11. Mayr, A., H.Mahnel und E.Munz (1971):
Zum Problem einer Fremdvirus-Kontamination von Menschenpocken-Impfstoffen (Dermo-Vaccinen vom Rind und Schaf).
Zbl.Vet.Med.B **18**, 679-691.

12. Rivers, T.M. (1931):
Cultivation of vaccinia virus for Jennerian prophylaxis in man.
J.exp.Med. **54**, 453-459.

13. Sutter, G. (1989): Das Genom des Vacciniavirus-Stammes Ankara und seine Veränderungen während der Attenuierung.
Vet.Med.Diss. München.

Table 1

History of Variola

Period of time	Country	Documentation
Several thousand years BC	Central-Asian origin	Historical analyses
1,5000 BC	India	Goddess of the Pox Sanskrit
1122 BC	China	Old writings
2,000 BC to 400 AD	Egypt, Greece, Roman Empire	Under various names in old writings
570 AD	France	**Marius of Avenches** Term "variola" used for first time
900 AD	Persia, Arabia	**Zakarja Razi** Precise description of smallpox
Middle Ages 1838	Europe, America, Africa Australia	Reports of spread of smallpox to all continents through wars, trade, slavery
1870-1873	Germany (commencement of vaccination era)	Last large-scale **pandemic** (100,000 deaths)

Table 2

Development of smallpox vaccination

Time	Type of prophylaxis	Outcome	Documentation
Long before Christ: Chinese and Indian empires	**Inoculation** of children with dried smallpox scabs via the nose or skin	Localised, mild to severe generalised variola, specific protection against epidemics	Detailed reports of **"healers"** of those times
Early history: South America	Inoculation of children with **cowpox**	Mild to severe pox disease, protection against death from smallpox	Oral accounts, no scientific reports
17th century: Near East, Europe	**Variolation** pustule material administered to children percutaneously at so-called **smallpox centres**	Mild to severe smallpox infection Protection from epidemics, changes in course of the epidemic	Documentation in publications and medical textbooks
1774 England	Cowpox material administered to children	Localised smallpox pustules	Farmer **Jesty**, no scientific documentation, oral accounts
1780 England	Widespread application of and precise directions for **variolation**	Localised smallpox pustules	**William Kullen** scientific publication
1791 Germany (Schleswig-Holstein)	**Cowpox** pustule material administered cutaneously to children	Localised smallpox pustules	Schoolmaster **Plett**, no scientific documentation
1796 - 1798 England	**Cowpox** pustule material administered to children, term **vaccine** used for first time	**First experimental proof** of protection against variola	**Edward Jenner**, publications, books
1799 - 1980	Worldwide vaccination with vaccinia virus, live-virus vaccine	Rapid decline in number of smallpox epidemics until eradication in 1980	Numerous publications and scientific works

Table 3

History of Smallpox Vaccines

Time	Type	Special features
1798 to mid-19th century	**Humanised vaccine** child-child-child (inoculation with Jenner's vaccine)	Diminished virus titre and virulence - too few children as "donors" (orphans and foundlings) - contamination
19th century	**1st generation of retrovaccines** child-rabbit-child	– – low virus titre – contamination
1856	**2nd generation of retrovaccines** child-cow-child	– – improved retrovaccine – regeneration of virus
End of 19th century - 1980	**Bovine dermovaccine**	– – Vaccine recommended by the WHO, – **used worldwide**
1911 - 1955	**Donkey dermovaccine**	Use in: Turkey, Near East
as of 1952	**Egg vaccine**	Only experimental use, not officially authorised
1905 - 1953	**Vaccine from inactivated vaccinia virus**	Not efficacious
As of 1960	**Cell-culture vaccine**	Only experimental application, not officially authorised
1972 - 1980	**MVA vaccine** first parenteral smallpox vaccine	**Officially authorised** approx. 150,000 primary vaccinations

Note: except for the MVA vaccine, all smallpox vaccines were administered cutaneously, intracutaneously or percutaneously

Table 4

History of MVA

Time	Status	Assessment
1798 - 1980	Immunisation against smallpox with vaccinia vaccines of varying virulence (cutaneous)	– high percentage of postvaccinal complications in the case of initial vaccinations – cutaneous contamination with human, rabbit and bovine organisms
1905 - 1953	Experiments with vaccines from inactivated vaccinia virus	No protective effect
1960 - 1974	572 passages of the **Ankara** dermovaccinia virus in primary chicken embryo fibroblast cultures (CEF) by **A. Mayr**	– adaptation to CEF cultures – mutation selection processes during passages – optimal propagation in the cell cultures with titres up to $10^{8.0}$ KID_{50}/ml
1974	CEF-passaged **Ankara** strain is given the name **MVA** (modified vaccinia virus Ankara)	– genetically stable with deletions – restricted host range – greatly diminished virulence for humans and animals – reduced contagiousness – parenteral application without complications – biological markers
1976	MVA officially approved for parenteral staged vaccination of children	– subcutaneous initial vaccination of 150,000 children without complications
1980 - 1998	MVA vaccine for voluntary immunisation of humans and animals	– twofold parenteral vaccination for protection **no postvaccinal complications**
1992 - 1998	MVA as vector for foreign antigens	– insertion of numerous genes of varying origin – good expression – optimal antigen realisation

Figures

EXHIBIT G

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington DC

Before the Honorable Robert L. Barton, Jr.
Administrative Law Judge

In the Matter of
Certain Modified Vaccinia Ankara ("MVA")
Viruses and Vaccines and Pharmaceutical
Compositions Based Thereon

Inv. No. 337-TA-550

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Deposition of:
MR ANTON MAYR

taken at the offices of:
Bird & Bird
Pacellistrasse 14
Munich
Germany

on Wednesday, 14th December 2005
commencing at 9.01 am

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A. Yes. That is my signature.
Q. Do you remember ever seeing this document before today?
A. I do not recall.
Q. Let me direct your attention to page 3 of the document, paragraph 5. In the German version of this paragraph does it indicate that you provided rights to Bavarian Nordic in the year 2002?
A. Yes.
Q. Does the document refresh your recollection as to when you gave Bavarian Nordic rights?
A. Yes.
Q. Did you give rights to Bavarian Nordic in the year 2002?
A. I don't know whether it was 2002, but I do recall that I provided Bavarian Nordic with exclusive rights to all MVA -- MVA, yes.
Q. Do you know -- please.
A. Let me add the following to paragraph 5. Of course there were many PhD candidates working in my lab, my institute, and all were interested what was done in my own lab. I do not know who of these co-workers used the strain for scientific purposes.
Q. Do you know a gentleman by the name of Bernard Moss?
A. Yes.
Q. Have you ever sent to Dr Moss samples of MVA viruses?
A. Yes.

Q. Have you ever told Dr Moss in sending those samples that he was restricted in how he could use them?

A. I did not do so, because the exchange of viruses or strains on an international level is customary without imposing restrictions.

Q. In any written agreements you have signed with Bavarian Nordic by which rights were provided do you recall if the agreements were in English or German?

A. I believe in English, but I don't know.

Q. Do you understand what the English word "access" means?

A. No.

Q. Could the translator translate the word "access" in German?

A. And I would like to make a general comment. The meaning of --

Q. I think we need to transcribe the translator's comments at this moment. It is an important word. So the record is clear, I am asking the translator to give us a German word that's the equivalent of "access" and spell the word in German so the court reporter can transcribe that.

INTERPRETER: Zugang. Z -- the witness asked whether he would be permitted to comment and I asked to be allowed by the witness to complete the spelling first.

Z-U-G-A-N-G and then Z-U, but lower case Z, and I would

MR COSTON: Can you identify this letter?
A. This is right. Yes.
Q. Who is Professor Dorner?
A. Professor Dorner did his dissertation or thesis with me. Then I believe he went to Bering and where he is currently I do not know, but he is an excellent scientist and he kept receiving new offers of employment.
Q. In this letter were you sending Professor Dorner some MVA virus?
A. That is correct. Professor Dorner did his thesis in my lab and he is familiar with this strain.
Q. The last sentence refers to the Lösung, L-O-S-U-N-G, and then there's a number. To what does that refer?
A. This refers to the fact that the virus is kept in physiological solutions. Then you titre the virus according to millilitre and then you determine the culture infectious dosage, which here is KID in 50 ml. The number must always be above 10 to the 6 and you always indicate what it actually is.
Q. Why must the number always be above 10 to the 6th?
A. Because you need a certain number of viruses or bacteria in millilitres for an infectious dosage.
Q. Let's mark the next exhibit "79", which is a letter of September 19, 1995 from Professor Mayr to Dr Bernard

Moss.

(Defendants' exhibit 79 marked and dated by court reporter)

Q. Can you identify this exhibit?

A. Yes.

Q. And what is it, please?

A. Dr Moss is the head of the ...

Q. Give your answer in German so that the translator can ...

A. Dr Moss is at the NIH in Bethesda. He is very reputable. I also believe that he is the director, and we always have an interest in as many individuals as possible working with MVA.

Q. Does this letter indicate that you sent him MVA?

A. Yes. Yes, two vials of the 575th passage on CEF and three samples of vaccinia virus MVA. All these samples were freeze-dried.

Q. Exhibit 80 is a September 12th, 2001 letter from Professor Mayr to Professor Moss.

(Defendants' exhibit 80 marked and dated by court reporter)

Q. This has Bates number 91944. Can you identify this document, please?

A. Yes.

Q. What is it, please?

A. I stated or I indicated to Mr Moss that there were publications on MVA and I think I specifically cite the

as 572.

MR PENNINGTON: When you sent samples to Dr Moss, did you have an understanding as to whether or not the NIH was a research institution or a commercial institution?

MR COSTON: Object to the form of the question. Leading. Compound.

A. Until today I have always -- and it is my continuing opinion -- always assumed that NIH is not a commercial institution but a pure research institute.

MR PENNINGTON: And when you gave samples to NIH, did you believe that you gave them permission to use the samples commercially?

A. No, no, no.

MR COSTON: Object to the form of the question. Leading. Assumes facts not in evidence.

MR PENNINGTON: Could you translate and then take the answer?

A. I never assumed when I sent samples or a sample to NIH, no matter which sample it was, that NIH would use it for commercial purposes and that continues to be my opinion today. I must add that I also have no information that NIH pursues commercial purposes.

Q. I believe you testified earlier today that you gave strains of MVA out to other researchers. Is that correct?

A. Yes, but only for research purposes.

Q. Do you have a view as to whether or not the people who received your samples understood that it was only for research purposes?

MR COSTON: Object to the form of the question. Leading. Calls for speculation.

A. That is what I must assume.

MR PENNINGTON: Do you know if there is an understanding in the academic and research community that if you receive a viral sample from a scientist that it is only for research purposes --

A. Yes.

Q. -- as opposed to commercial purposes?

MR COSTON: Objection. Compound. Leading. Calls for speculation. Calls for expert opinion without disclosure of expert qualifications.

A. That is my opinion, yes.

MR PENNINGTON: Does your opinion extend worldwide or just in Germany?

A. Worldwide.

MR COSTON: Object to the form of the question. Compound. Leading. Calls for undisclosed expert opinion and no foundation.

MR PENNINGTON: Did you get his answer?

COURT REPORTER: Yes.

A. Yes, I did testify to that effect, and I can explain now even better. When we send the strain to a research institute, we definitely assume that they won't use it, only for research purposes and for nothing else.

Q. I have no further questions.

A. Thank you very much.

Re-direct examination by MR COSTON:

MR COSTON: I just have two, two more. I get to follow on. Earlier you testified that one cannot obtain a patent on technology that is in the public domain. Do you recall that testimony?

A. Yes.

Q. So that if there were no patent protection available, anyone could use that technology. Correct?

A. Yes, if it has been published, if it is published --

MR PENNINGTON: Objection. Calls --

A. -- in a journal or -- I think journal.

Q. Objection. Calls for expert opinions on matters related to patent and other intellectual property laws for which the witness is not qualified.

MR COSTON: Okay. You may please translate the answer.

A. It is correct that I'm not an expert on patent and IP law. I do know, however, from discussion with other researchers that patents can be obtained only for innovations and not for anything that has already been

published. Yes. That's right. Yes. The subject of the patent may not have been published on except for within the range of the six months preceding the patent application.

Q. Let me see if I understand the answer you gave prior to that answer, and that is that if the technology is in the public domain such that it may not be patented, do you have an understanding then that anyone in the public may use the technology?

MR PENNINGTON: Objection. Calls for legal speculation. Calls for opinions involving legal matters for which the witness is not qualified to answer.

INTERPRETER: Would you mind reading the question back to me? Thank you.

(Question read back by court reporter)

MR PENNINGTON: Further objection for mischaracterising prior testimony.

A. Yes, may use the technology, yes. If the publication was in a reputable technical journal and there is no patent, then anyone can use the technology.

MR COSTON: Thank you very much.

MR PENNINGTON: Are you done?

MR COSTON: Yes.

Further cross-examination by MR PENNINGTON:

MR PENNINGTON: I have one follow up. When you were

EXHIBIT H

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S and ANTON MAYR Plaintiffs, v. ACAMBIS INC. and ACAMBIS PLC, Defendants.	Civil Action No. 05-614 (SLR)

EXPERT REPORT OF DAVID EINHORN

Introduction

I have been retained by Bavarian Nordic A/S("Bavarian") in connection with this litigation pending before the U.S. District Court of Delaware to study and provide my opinion on certain issues relating to the customs of sharing, ownership and licensing of biological materials within the biomedical research community. In this litigation I understand that Bavarian claims that its proprietary technology in modified vaccinia Ankara("MVA") is being used without Bavarian's permission and for commercial purposes by Acambis Plc ("Acambis").

I hold a Bachelor of Science in Economics degree from the Wharton School of Finance and Commerce of the University of Pennsylvania, have studied at the London School of Economics and Political Science, and have a law degree from Georgetown University. I have practiced law in the States of New Jersey, New York and Maine and am currently employed as House Counsel of The Jackson Laboratory, 600 Main Street, Bar Harbor, Maine 04609. Over the past 16 years at The Jackson Laboratory, I have been involved in drafting, negotiating, approving and executing scores of legal documents involving the exchange, licensing and distribution of biological materials to and between academic, nonprofit, governmental, and forprofit entities. I am familiar in this context with material transfer agreements, license agreements, confidentiality agreements, collaborative research agreements, consulting agreements, etc., both with respect to patented and unpatented biological materials, and have negotiated such agreements with well more than 100 research institutions, both public and private, nonprofit and forprofit. I have also been involved in the provision of biological materials among scientists, including scientists at the National Institutes of Health("NIH"), that have not been accompanied by formal written agreements. I have been a speaker at conferences on technology transfer held by the Association of University Technology Managers, have lectured in Germany and Japan on technology transfer issues, and have worked with the National Institutes of Health on technology transfer issues of public concern. Additional information on my background is set forth in my curriculum vitae, which is annexed to this Report.

I am being compensated at a rate of $350 per hour in this matter. I have never testified as an expert witness at a trial. I was deposed in concurrent litigation between these parties before the International Trade Commission.

In forming the opinions expressed below, I have reviewed documents provided by counsel for Bavarian, including those relating to the transfer of the MVA from Professor Anton Mayr to Therion Biologics and to Dr. Bernard Moss of the National Institute of Allergy and Infectious Diseases("NIAID") and from NIAID to Acambis, as well as other documents addressing the issues in this matter, including those listed in Exhibit A.

I have not yet selected or prepared any trial exhibits to supplement my testimony or to illustrate my opinions.

Expected Testimony and Opinions

1. I am prepared to testify that when biological materials are shared or exchanged for "research purposes", "for research purposes only", or language of a similar nature, it is commonly understood in the academic, nonprofit, governmental and forprofit communities that the biological materials can only be used by the recipient of the materials for research and not for any "commercial purposes". It is further commonly understood that "commercial purposes" as distinguished from "research purposes", means sale of the biological materials or using the materials to manufacture something else for sale.

2. I am further prepared to testify that the sharing of biological materials among scientists is at the heart of the research commonly ethos that sharing will facilitate the advance of scientific knowledge in the public interest; and although the shared biological materials are often not accompanied by formal written agreements, that it is customarily understood that such shared materials are to be used by the recipient for research and not for commercial purposes. In this context, I believe that both Professor Mayr and Dr. Moss, as fellow academic and governmental researchers, understood that biological materials shared between them would be used for research and not for commercial purposes.

3. I may testify with respect to customs in the biomedical research community with respect to the transfer of research tools and NIH policies on sharing research tools.

4. I am further prepared to testify that it is commonly understood in the academic, nonprofit, governmental and forprofit communities that when the parties intend to have a formal legal document accompany the sharing of biological materials, the usual form is a material

transfer agreement. A material transfer agreement usually provides a recitation that ownership of the materials is claimed by the provider; that usually there is no consideration expected by the provider from the recipient other than the cost of the materials and/or shipping costs; that there is no transfer of intellectual property rights in the materials from the provider to the recipient; and that the recipient is only allowed to use the materials for its own research purposes. In distinction from a material transfer agreement, a license agreement normally provides for financial or other valuable consideration paid by the recipient to the provider for a grant of rights to use the materials for commercial purposes.

5. I have reviewed the document entitled, "Material Transfer Agreement" executed by NIAID and Acambis, wherein NIAID agreed to provide MVA to Acambis, and I am prepared to testify that this Material Transfer Agreement is unusual since it does not recite proprietary or ownership rights by NIAID in the MVA and purports to grant rights to use the MVA for commercial purposes. The grant of a commercial license in the Material Transfer Agreement is also I believe inconsistent with the non-commercial sharing of MVA material between two research scientists.

6. I may also testify from review of relevant documents and my understanding of customary practices typical of dealings between academics and companies, with respect to the following transactions :

a. Bavarian's acquisition of commercial rights to MVA from Professor Mayr through written agreements as the customary way by which companies obtain proprietary rights to biological materials.

b. Therion Biologics Corporation("Therion") efforts to obtain MVA from Professor Mayr and his insistence on restricting Therion's use for research purposes.

7. I am also prepared to testify that Professor Mayr's conduct in freely sharing MVA with Dr. Moss, and Professor Mayr's quite different response to the requests for MVA from commercial companies like Therion and Acambis, was typical of a basic research scientist who would assume based on the customs in the community that a researcher at the NIH would only

use MVA for research purposes, in contrast to a company like Therion which would be expected to be interested in MVA because of its commercial potential and from which Professor Mayr therefore took the precaution of requiring that MVA be used for research purposes only.

8. I may also be asked to testify about transactions in this case involving MVA, including agreements between Acambis, Therion and Baxter and Acambis and Baxter and transactions between Bavarian Nordic and other entities involving MVA.

9. I may also be asked to testify about the RFP process, the RFP's relevant to this case, the requirements for responses to those RFP's and the responses of Acambis and Bavarian Nordic to those RFPs.

I may supplement this Report if I become aware of additional pertinent information or in response to the testimony or reports of others.

Dated: 10/12/06

David Einhorn

EXHIBIT A

1. The Material Transfer Agreement for the transfer of MVA from NIH to Acambis.

2. Documents between Acambis, Bavarian Nordic, Therion, NIH, Anton Mayr, and others regarding the transfers of the MVA strain at issue in this case.

3. ITC Complaint and Exhibits attached to the original Complaint, including scientific data, secrecy and transfer agreements, RFPs 1 and 2, and Published articles regarding Acambis' and BN's strategic and financial positions; and the Answer.

4. Amended complaint and exhibits attached thereto, as filed in the Delaware case.

5. U.S. Patent Nos. 6,913,752 and 6,761,893

6. Bavarian Nordic Confidentiality Agreements with NIH and Acambis.

7. Higgins Memo reflecting IP position on Therion MVA, Bates number TBC00592 et seq.

8. German Opinion to Therion re MVA IP rights, Bates number TBC00013 et seq.

9. Correspondence between Acambis, Bavarian Nordic, Therion, NIH, Anton Mayr, and others regarding the transfer of the MVA strain.

10. November 6, 2002 letter from Anton Mayr to Bernard Moss requesting details of his activities with MVA obtained from Mayr.

11. November 6,1997 letter from Geoffrey Smith to Anton Mayr requesting permission to transfer MVA samples to Professor Dave Rowlands of the University of Leeds.

12. August 4, 1997 letter from Tom Blanchard to Anton Mayr requesting permission to transfer MVA samples to Professor Warwick Britton.

13. September 26, 1995 Declaration of Value regarding transfer of MVA strain from Anton Mayr to Therion Biologics Corp.

14. 1995 correspondence between Bernard Moss and Anton Mayr regarding request for MVA-575 strain.

15. 2002 correspondence between Therion Biologics Corp. and Anton Mayr regarding request for MVA-572 strain.

16. March 30, 1998 consulting agreement between Bernard Moss and with OraVax, Inc.

17. The Non-Confidential version of Acambis' Response to the ITC complaint.

18. Acambis' Response to Bavarian Nordic's Amended Delaware Complaint.

19. November 26, 1997 correspondence between Peter Wulff and Bernard Moss regarding patent no. WO 97/02355.

20. September 21, 2001 letter from Anton Mayr to Bernard Moss describing MVA-572 strain sent from Mayr to Moss.

21. June 30, 2003 letter from Peter Wulff to Anton Mayr attaching new consultancy agreement.

22. July 4, 2003 letter from Anton Mayr to Peter Wulff regarding consultancy agreement and Mayr's research.

23. November 1997 email correspondence between Peter Wulff and Geoffrey Smith regarding transfer of MVA strain.

24. February 2000 correspondence between Paul Howley and Anton Mayr regarding development of MVA strain.

25. June 2002 facsimile of statement from Anton Mayr that he provided Bavarian Nordic with the Elstree Vaccinia strain.

26. 2002-2003 correspondence between Bavarian Nordic, the NIH, Bernard Moss, Acambis, and Anton Mayr regarding rights to use MVA.

27. August 21, 2002, email from Thomas Monath to various Acambis employees relating a conversation between Monath and Bernard Moss re: Acambis' intention to use an MVA strain obtained from Therion Biologics Corp.

28. April 14, 2002 letter from Acambis to NIAID attaching confidential disclosure agreement.

29. January 17, 2003 letter from Roger McAvoy to Jacqueline Holden of NIH regarding Acambis' failure to conduct an analysis of third-party intellectual property rights in MVA.

30. January 17, 2003 letter from Michael Mowatt to Roger McAvoy urging Acambis to conduct an analysis of third-party intellectual property rights in MVA

31. November 27, 2002 cover letter and Materials Transfer Agreement between the NIH and Acambis.

32. February 26, 2002 Secrecy Agreement between Bavarian Nordic and Acambis.

33. December 10, 2002 letter (redacted) from Therion to Acambis regarding Therion's asserted intellectual property position regarding MVA.

34. The Confidential version of Acambis' Response to the ITC complaint.

35. Acambis' Answer to Bavarian Nordic's Amended Complaint filed in the Delaware case.

36. Anton Mayr's Confidential declaration included as an exhibit to Bavarian Nordic's Opposition to Acambis' Motion to Terminate, regarding Mayr's transfer of MVA strains.

37. Correspondence between Therion Biologics Corp. and Acambis regarding termination of their agreement to use an MVA strain supplied by Therion.

38. Deposition Transcript of Nick Higgins (August 26, 2006) and exhibits.

39. Deposition Transcript of Roger McAvoy (September 15, 2006) and exhibits.

40. Deposition Transcript of Bernard Moss (August 28, 2006) and exhibits.

41. Deposition Transcript of Anton Mayr (September 21, 2006) and exhibits.

42. Deposition Transcript of Anton Mayr (December 14, 2005) and exhibits.

43. Bavarian Nordic and Oxxon License.

44. Bavarian Nordic and Transgene License.

45. "Journal of General Virology Instructions for Authors," HTML version last modified 25 August 2006, printed from http://vir.sgmjournals.org/misc/ifora.shtml, with instructions for online submissions of papers for publication.

46. "JCB – Instructions to Authors," printed from http://www.jcb.org/misc/ifora.shtml, with instructions for submission of manuscripts.

47. Journal of Virology, Jan. 2006, p. 1-17, article entitled "2006 Instructions to Authors."

48. Expert Report of Prof. Joseph Straus.

49. Anton Mayr-Bavarian Nordic Agreement 1 June 1996.

50. Anton Mayr-Bavarian Nordic Agreement 1 June 1999.

51. Anton Mayr-Bavarian Nordic Agreement 1 June 2001.

52. Anton Mayr-Bavarian Nordic Agreement 1 June 2003.

53. Anton Mayr-Bavarian Nordic Agreement 6 Nov 2002.

54. Anton Mayr-Bavarian Nordic Agreement 19 Apr 2004.

55. Anton Mayr-Bavarian Nordic Agreement 24 Mar 2004.

56. Anton Mayr-POA and Rights. (BNDEL001269).

57. August 3, 2001 Dr. Moss Letter to Anton Mayr. (BNDEL001259).

58. September 12, 2001 Anton Mayr Letter to Dr. Moss.

59. September 14, 1995 Dr. Moss Letter to Anton Mayr.

60. September 19, 1995 Anton Mayr Letter to Dr. Moss.

61. Article by H. Stickl, V. Hochstein-Mintzel, A. Mayr, H. Ch. Huber, H. Schäfer and A. Holzner, entitled "MVA Vaccination Against Smallpox; Clinical Tests with an Attenuated Live Vaccinia Virus Strain (MVA)," Dtsch. med. Wschr. 99 (1974), 2386-2392.

62. Article by H. Stickl and V. Hochstein-Mintzel, entitled "Intracutaneous Smallpox Vaccination with a Vaccinia Virus Having Attenuated Virulence ("MVA virus")," Social Medicine and Hygiene, from the Bavarian State Vaccination Institute, Munich (Director: Prof. H. Stickl, M.D.).

63. DBM0001-0097.

CURRICULUM VITAE
DAVID EINHORN, ESQ.

PERSONAL

Address: 26 Atlantic Avenue
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Telephone: (207) 288-9791
Date of Birth: October 31, 1940
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Children: Jesse Aaron

EDUCATION

Passaic High School, Passaic, New Jersey

Wharton School of Finance and Commerce
University of Pennsylvania (B.S.E.)
(1962)

London School of Economics and Political Science,
University of London (1960-1961)

Georgetown Law School
Georgetown University (L.L.B.) (1965)

EMPLOYMENT

Civil Rights Clerkship Smith, Waltzer, Jones and Peebles, Esqs.
New Orleans, Louisiana (1964)

Associate of Sellinger and Chester, Esqs.
Passaic, New Jersey (1965-1967)

Private general practice at 21 East 40th Street, New York City,
and 307 Monroe Street, Passaic, New Jersey, (1968-1969)

Executive Director of Union County Legal Services Corporation
(1969-1974)

Special Assistant for Legal Affairs State of New Jersey
Department of Institutions and Agencies (1974-1976)

Deputy Commissioner, State of New Jersey Department of Human
Services (1976-1979)

Consultant to Daniel and Florence Guggenheim Foundation
Project on Criminal Justice at Princeton University and Yale Law
School (1981)

Private general practice in Milford, New Jersey (1982-1985)

Consultant to the Legal Services Corporation, Washington, D.C.
(1985)

Of Counsel with Fenton, Chapman, Fenton, Smith and Kane,
Esqs. Bar Harbor, Maine (1986-1994)

House Counsel, The Jackson Laboratory, Bar Harbor, Maine

(1989-Present)

BAR ADMISSIONS

Admitted to the New Jersey Bar (1965)(inactive)
Admitted to the New York Bar (1968)(inactive)
Admitted to the Maine Bar (1986)

ASSOCIATIONS

Past Member of the Union County, Passaic County and Hunterdon County Bar Associations

Past lecturer of the New Jersey Institute for Continuing Legal Education Skills Training Course

Past Member of the New Jersey Public Employment Relations Commission Panel of Grievance Arbitrators

Past Arbitrator of the American Arbitration Association

BOARDS

Past Chairman, Town of Bar Harbor Planning Board
Past Chairman, State Advisory Council to the New Jersey Department of Corrections
Past Member, Board of Peter W. Rodino Institute for Criminal Justice
Past Member, Mental Health Association of Hunterdon County, New Jersey

TEACHING

Criminal Justice Program Woodrow Wilson School of Public and International Affairs, Princeton University (1976)

Adjunct Faculty, College of the Atlantic, Bar Harbor Maine

PUBLICATIONS

"Sharing Research Tools: The Laboratory Mouse" Sundberg JP, Ichiki T (eds.), Handbook on Genetically Engineered Mice, CRC Press, Boca Raton, Fl. (in press)

EXHIBIT I

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S, Plaintiff, v. ACAMBIS INC. and ACAMBIS, PLC, Defendants.	Civil Action No. 05-614

EXPERT REPORT OF ROBERT DRILLIEN

I. INTRODUCTION

1. My name is Robert Drillien and I hold a position at the Institute of Genetics and Molecular and Cellular Biology ("IGBMC") in Strasbourg, France, which is one of the leading European Centers for biomedical research. My own research focuses on virology with emphasis on the analysis of vaccinia virus strains such as Modified Vaccinia Ankara ("MVA").

2. I have been retained as a scientific expert by Bavarian Nordic A/S ("BN") in connection with the above-referenced lawsuit to study and provide my opinion on certain issues relating to academic research and biopharmaceutical industry practices.

3. I understand that BN claims that a specific biological material referenced to as MVA-572 has been unlawfully converted by Acambis, which I understand is one of the allegations of unfair trade practices raised against Acambis in this case.

II. QUALIFICATIONS

4. I hold a Bachelor of Science degree in Biochemistry, a Master in Biochemistry and a Ph.D. in Virology. I have essentially conducted scientific research in academia since 1970 and have specifically focused on the field of virology for the past 30 years. At the academic level I collaborate with researchers globally in the field of Poxviruses (the family of viruses that includes vaccinia virus and the smallpox virus known as variola) and I am a member of the World Health Organization ("WHO") Advisory Committee on Variola Virus Research, reviewing the progress of research involving live variola virus.

5. I am being compensated at a rate of $200 per hour in this matter. I have previously testified as an expert and been deposed for trial in concurrent litigation between these parties before the International Trade Commission. I have also been retained as an expert in concurrent litigation between the parties at the Commercial Court of Vienna, Austria. Aside from these companion cases, I have never previously testified as an expert or been deposed for trial, nor been retained as or testified as an expert on this subject matter in any other litigation.

6. In forming the opinions expressed below, I have reviewed and relied on my knowledge -- encompassing more than 30 years of research -- in the field of Poxviruses, including the specific field of vaccinia virus and MVA, and certain documents listed in Exhibit A.

7. I have not selected or prepared any trial exhibits to supplement my testimony and illustrate my expressed opinions at this time.

III. EXPECTED TESTIMONY AND OPINIONS

8. I am prepared to provide an overview of MVA technology at issue in this case and to testify about MVA strains and their history and qualities; the history of smallpox disease

and vaccines against smallpox; and vaccines against smallpox and other diseases based on the MVA virus. I am also prepared to testify about how organizations, such as the WHO, and nations respond to smallpox and other threats of disease and biological weapons.

9. I am prepared to testify on the conversion of the MVA-572 strain by Acambis for Acambis' commercial use, the significance of access to this particular MVA strain to achieve an expeditious development of an MVA vaccine product to pursue a Biologic License Application ("BLA") at the FDA. Use of this particular strain because of the year of its creation enables one to avoid certain regulatory hurdles and warning labels relating to bovine spongiform encephalopathy ("BSE") and/or transmissible spongiform encephalopathy ("TSE"). Thus, MVA-572 is an important and desirable MVA virus material.

10. I am prepared to testify about how access to MVA biological material, including the Therion MVA virus or MVA-572, grown up into a seed stock at NIH, was necessary for Acambis to bid on RFP 1, 2 and 3 and receive contracts to supply over 505,000 doses of MVA vaccines to the U.S. Government.

11. I am prepared to testify that Acambis made commercial use of the seed stock received from NIH for Acambis' smallpox vaccine product MVA3000, also sometimes called ACAM3000.

12. I am prepared to testify about research and industry practices regarding the provision of live biological material, such as MVA virus strains, among scientists associated, including scientists associated with research institutions. I am prepared to testify that in such circumstances, without an explicit agreement that the strain may be used for commercial purposes, the live biological material or strain cannot be used for commercial purposes.

13. In particular, it is my opinion that the transfer of live biological material to a

research institution, absent a written agreement, takes place with the understanding that the biological material's use will be limited to research purposes only.

14. Moreover, it is my opinion that it is industry practice for a research institution to enter into an explicit, written agreement, when the exchange of biological material is intended for commercial purposes, such as the development of a commercial product.

15. I may be called upon to testify about research and industry practices within the scientific community in Europe and the U.S., regarding the provision of live biological material, such as MVA strains, to a research institution. In particular, it is my opinion that the transfer of live biological material to a research institution, absent a written agreement, takes place with the understanding that the biological material's use will be limited to research purposes only. Moreover, it is my opinion that it is industry practice for a research institution to enter into an explicit, written agreement, when the exchange of biological material is intended for commercial purposes, such as the development of a commercial product.

IV. MATERIALS CONSIDERED

16. I have attached to this report a list of materials that I reviewed and considered in forming the basis for my opinions.

17. I reserve the right to continue to review materials that have been produced in this case, and supplement my expected testimony based on the review of such additional materials. I further reserve the right to review the reports of other experts in this case, including any experts put forth by Acambis, and supplement my opinions based on any such reports.

Respectfully submitted, October 12, 2006

Robert Drillien
14 rue Waldteufel
Strasbourg, France

EXHIBIT A

1. Bavarian Nordic's ITC Complaint (Inv. No. 337-TA-550) and Exhibits attached to the original Complaint; and the Confidential version of Acambis' Response to the ITC complaint.

2. Bavarian Nordic's Delaware Amended Complaint (Civil Action No. 05-614 (SLR)) and Exhibits attached to the original Complaint; and Acambis' Response to the Delaware complaint.

3. U.S. Patent Nos. 6,913,752 and 6,761,893.

4. Bavarian Nordic's interrogatories responses in the ITC case (Inv. No. 337-TA-550) and the Delaware case.

5. Acambis' interrogatory responses in the ITC case (Inv. No. 337-TA-550) and the Delaware case.

6. The 30(b)(6) Deposition transcript of Cynthia Lee (December 5, 2005) and exhibits in the ITC case (Inv. No. 337-TA-550).

7. The Deposition transcript of Dr. Robert Drillien March 8, 2006, and exhibits in the ITC case (Inv. No. 337-TA-550).

8. The Deposition transcript of Dr. Robert Drillien March 9, 2006, and exhibits in the ITC case (Inv. No. 337-TA-550).

9. The Deposition transcript of Dr. Miles Carroll, and exhibits (March 1, 2006).

10. The Deposition transcript of Dr. Miles Carroll, and exhibits (March 2, 2006).

11. The Deposition transcript of Dr. Miles Carroll, and exhibits (July 23, 2006).

12. The Expert Report of Dr. Milles Carroll, and exhibits in the ITC case (Inv. No. 337-TA-550).

13. The Expert Report of Dr. Robert Drillien, and exhibits in the ITC case (Inv. No. 337-TA-550) (RX-273C:1-13).

14. The Rebuttal to Expert Report of Dr. Milles Carroll and to the Technical Aspects of the Expert Report of Michael Sofocleous, and exhibits in the ITC case (Inv. No. 337-TA-550).

15. The Rebuttal to Expert Report of Dr. Robert Drillien, and exhibits in the ITC case (Inv. No. 337-TA-550).

16. The Expert Report of Dr. Leonard Schultz, and exhibits in the ITC case (Inv. No. 337-TA-550).

17. Dr. Robert Drillien's Witness Statement from the ITC case (Inv. No. 337-TA-550) (CX-243C-1-122).

18. Dr. Miles Carroll's Witness Statement from the ITC case (Inv. No. 337-TA-550) (RX-649C:1-153; RX-650C:1-121).

19. The trial hearing testimony of Dr. Milles Carroll from the ITC case (Inv. No. 337-TA-550).

20. The trial hearing testimony of Dr. Robert Drillien from the ITC case (Inv. No. 337-TA-550).

21. VIVACS # 1200104 (aka Vivacs 1) from the ITC case (Inv. No. 337-TA-550) (RX-76C:1-20).

22. VIVACS 1200405 (aka Vivacs 2) from the ITC case (Inv. No. 337-TA-550) (RX-75C:1-45).

23. VIVACS 0100506 (aka Vivacs 3) from the ITC case (Inv. No. 337-TA-550) (RX-74C:1-81).

24. Scientific Report: Attenuation Profile Comparison of Various MVA-Strains w/Well plates (aka Drillien Study) [Tab D & D2] from the ITC case (Inv. No. 337-TA-550) (RX-289C:1-80).

25. Scientific Report: Attenuation Profile Comparison of Various MVA-Strains from the ITC case (Inv. No. 337-TA-550) (RX-288C:1-14).

26. University of Zurich Study Report: Attenuation profile comparison of various MVA-strains, dated March 2006 from the ITC case (Inv. No. 337-TA-550) (RX-25C:1-25).

27. Nucleotide Alignment MVA-Antoine vs. Acambis 3000 MVA vs. MVA-BN (CX-66C:1-431) from the ITC case (Inv. No. 337-TA-550).

28. 3/31/06 Baxter BioScience Report GAEX166 from the ITC case (Inv. No. 337-TA-550)(RX-254C:1-4).

29. 4/11/06 Baxter BioScience Report GAEX168 from the ITC case (Inv. No. 337-TA-550)(RX-255C:1-6).

30. Corrigendum to Antoine et al. Virology (1998) from the ITC case (Inv. No. 337-TA-550)(RX-256-.1-2).

31. The Initial Determination in the ITC case dated September 7, 2006 (Inv. No. 337-TA-550).

32. Complainant's Petition for Review of the Initial Determination in the ITC case (Inv. No. 337-TA-550).

33. Respondent's Petition for Commission Review of the Initial Determination in the ITC case (Inv. No. 337-TA-550).

34. OUII's Petition for Commission Review of the Initial Determination in the ITC case (Inv. No. 337-TA-550).

35. Complainant's Response To Respondent's Petition For Commission Review of the Initial Determination in the ITC case (Inv. No. 337-TA-550).

36. Complainant's Response To OUII's Petition For Commission Review of the Initial Determination in the ITC case (Inv. No. 337-TA-550).

CURRICULUM VITAE: ROBERT DRILLIEN

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Diplomas:

High School Diploma, 1964, New York, New York
Baccalauréat, 1966, Strasbourg, France
Bachelor of Science in Biochemistry (Biochemistry), 1970, University of Strasbourg, France
Masters in Biochemistry, 1972, University of Strasbourg, France
PhD in Virology 1981, University of Strasbourg, France

Training:

1970-1972:	Research training in the Genetics Laboratory (Professor François Lacroute) of the School of Science, University of Strasbourg
1981-1982:	Postdoctoral training in the Department of Virology, St. Mary's Hospital Medical School, London, Great Britain (Professor Keith Dumbell)

Positions:

1972-1976:	Junior research associate in the Virology laboratory (Professeur André Kirn) of the School of Medicine of the University of Strasbourg, France
1976-1981:	Research associate at the French National Institute of Health and Medical Research (INSERM): Laboratory of Pathogenesis of Viral Infections (Strasbourg, France) directed by Professor André Kirn
1981-1982:	Postdoctoral position in the Department of Virology, St. Mary's Hospital Medical School, London, Great Britain (Professor Keith Dumbell)
1982-1986:	Research associate at INSERM, Pathogenesis of Viral Infections directed by Professor André Kirn
1986-1988:	Temporary research position at Transgène (Strasbourg, France)
1988-1992:	Research associate at INSERM, Pathogenesis of Viral Infections directed by Professor André Kirn
1993-1996:	Senior investigator at INSERM, Pathogenesis of Viral Infections directed by Professor André Kirn
1996-2004:	Senior investigator at the INSERM laboratory EPI 99-08 (Director: Daniel Hanau) in the Etablissement Français du Sang (Blood Transfusion Center, Strasbourg)
2004-present:	Senior investigator at the INSERM laboratory of the IGBMC (INSERM U596),

Illkirch, France (Director : Jean-Louis Mandel)

Membership, committees and consultancies:

1996-present: French Gene Technology Committee (Commission de Génie Génétique).
1999-present: World Health Organization Advisory Committee on Variola Virus Research.

1996-present: American Society for Microbiology.
1996-present: British Society for General Microbiology.
2000-present: Advisor to the French Agency for the Security of Health Products (AFSSPS) on Poxviruses.
2002-present: Advisor to European Pharmacopoeia on Poxviruses.
1988-present: Consultant to Transgene (Strasbourg, France) generally on Poxviruses.
2002-November 2005: Consultant to Bavarian Nordic (Kvistgård, Denmark) generally on Poxviruses, unrelated to the technology of U.S. Patents No. 6,761,893 and No. 6,913,752.

Recent Publications (2000-2005)

Hsiao, J-C, Che-Sheng Chung, C-S, Drillien, R, Chang, W. The cowpox virus host range gene, CP77, affects phosphorylation of eIF2□ and vaccinia viral translation in apoptotic HeLa cells. Virology, 2004, 329, 199-212.

Drillien R, Spehner D, Hanau, D. Modified Vaccinia Virus Ankara induces moderate activation of human dendritic cells. J. Gen Virol. 2004, 85, 2167-2175.

Spehner D, De Carlo S, Drillien R, Weiland F, Mildner K, Hanau D, Rziha H.-J. The appearance of the bona fide spiral tubule of Orf virus is dependent on an intact viral 10 kDa Protein, J. Virol. 2004, 78, 8085-8093.

Drillien, R., Spehner, D., Garin, D. Les virus candidats à un vaccin antivariolique de troisième génération. Méd. et Mal. Inf. 2004, S51-S54.

Drillien R, Spehner D, Autran B, Garin D. Les Poxvirus : Une famille de vecteurs. Virologie, 2003, 7, 243-253.

Scaramozzino N, Sanz G, Crance JM, Saparbaev M, Drillien R, Laval J, Kavli B, Garin D. Characterisation of the substrate specificity of homogeneous vaccinia virus uracil-DNA glycosylase. Nucleic Acids Res. 2003 Aug 15;31(16):4950-7.

Spehner D, Drillien R, Proamer F, Hanau D, Edelmann L. Embedding in Spurr's resin is a good choice for immunolabelling after freeze drying as shown with chemically unfixed dendritic cells. J Microsc. 2002 July;207(Pt 1):1-4.

Lipsker D, Ziylan U, Spehner D, Proamer F, Bausinger H, Jeannin P, Salamero J, Bohbot A, Cazenave JP, Drillien R, Delneste Y, Hanau D, de la Salle H. Heat shock proteins 70 and 60 share common receptors which are expressed on human monocyte-derived but not epidermal dendritic cells. Eur J Immunol. 2002 Feb;32(2):322-32.

Spehner D, Drillien R, Proamer F, Houssais-Pecheur C, Zanta MA, Geist M, Doll K, Balloul JM.

Enveloped virus is the major virus form produced during productive infection with the modified vaccinia virus Ankara strain.
Virology. 2000 Jul 20;273(1):9-15.

Lipsker D, Spehner D, Drillien R, Schmitt P, Cribier B, Heid E, Humbel RL, Grosshans E.
Schnitzler syndrome: heterogeneous immunopathological findings involving IgM-skin interactions.
Br J Dermatol. 2000 May;142(5):954-9.

Drillien R, Spehner D, Bohbot A, Hanau D.
Vaccinia virus-related events and phenotypic changes after infection of dendritic cells derived from human monocytes.
Virology. 2000 Mar 15;268(2):471-81.

EXHIBIT J

4. *Ensure Dissemination of Research Resources Developed with NIH Funds*

Progress in science depends upon prompt access to the unique research resources that arise from biomedical research laboratories throughout government, academia, and industry. Ideally, these new resources flow to others who advance science by conducting further research. Prompt access can be accomplished in a number of ways, depending on the type of resource that has been developed, whether it has broad or specific uses, and whether it is immediately useful or private sector investment is needed to realize its usefulness. The goal is widespread, timely distribution of tools for further discovery. When research tools are used only within one or a small number of institutions, there is a great risk that fruitful avenues of research will be neglected.

Unique research resources arising from NIH-funded research are to be made available to the scientific research community. Recipients are expected to manage interactions with third parties that have the potential to restrict Recipients' ability to disseminate research tools developed with NIH funds.[1] For example, a Recipient might use NIH funds with funds from one or more third party sponsors, or acquire a research tool from a third party provider for use in an NIH-funded research project. Either situation may result in a Recipient incurring obligations to a third party that conflict with Recipient's obligations to the NIH. To avoid inconsistent obligations, Recipients are encouraged to share these Principles with potential co-sponsors of research projects and third party providers of materials.

Recipients should also examine and, where appropriate, simplify the transfer of materials developed with NIH funds to for-profit institutions for internal use by those institutions. NIH endorses distinguishing internal use by for-profit institutions from the right to commercial development and sale or provision of services. In instances where the for-profit institution is seeking access for internal use purposes, Recipients are encouraged to transfer research tools developed with NIH funding to such institutions without seeking option rights or royalties on the final product.

[1] Research tools obtained or derived from human tissues constitute a special case. Certain restrictions on the use and further dissemination of such tools may be appropriate to ensure consistency with donor consent and human subjects protection. See 45 C.F.R. Part 46.

SUMMARY

Access to research tools is a prerequisite to continuing scientific advancement. Ensuring broad access while preserving opportunities for product development requires thoughtful, strategic implementation of the Bayh-Dole Act. The NIH urges Recipients to develop patent, license, and material sharing policies with this goal in mind, realizing both product development as well as the continuing availability of new research tools to the scientific community.

These four basic principles should promote further research, enhance discovery, support a robust research enterprise, and improve public health.

FOR ASSISTANCE IN IMPLEMENTATION PLEASE REFER TO:

"Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts" at

http://ott.od.nih.gov/NewPages/RTguide_final.html
or
http://ott.od.nih.gov/NewPages/64FR72090.pdf

FOR FURTHER INFORMATION CONTACT:

Extramural Technology Transfer Policy Staff
NIH Office of Technology Transfer
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.
Telephone: (301) 496-7057
Fax: (301) 402-3257
E-mail: NIHOTT@od.nih.gov

2002.02

NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health (NIH)

Presents

SHARING BIOMEDICAL RESEARCH RESOURCES

PRINCIPLES AND GUIDELINES FOR RECIPIENTS OF NIH RESEARCH GRANTS AND CONTRACTS

December 1999

THE PRINCIPLES

NIH Office of Technology Transfer
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804
U.S.A.
http://ott.od.nih.gov

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CX-43:1-2

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1. *Ensure Academic Freedom and Publication*

Academic research freedom based upon collaboration, and the scrutiny of research findings within the scientific community, are at the heart of the scientific enterprise. Institutions that receive NIH research funding through grants, cooperative agreements or contracts ("Recipients") have an obligation to preserve research freedom, safeguard appropriate authorship, and ensure timely disclosure of their scientists' research findings through, for example, publications and presentations at scientific meetings. Recipients are expected to avoid signing agreements that unduly limit the freedom of investigators to collaborate and publish, or that automatically grant co-authorship or copyright to the provider of a material.

Reasonable restrictions on collaboration by academic researchers involved in sponsored research agreements with an industrial partner that avoid conflicting obligations to other industrial partners, are understood and accepted. Similarly, brief delays in publication may be appropriate to permit the filing of patent applications and to ensure that confidential information obtained from a sponsor or the provider of a research tool[1] is not inadvertently disclosed. However, excessive publication delays or requirements for editorial control, approval of publications, or withholding of data all undermine the credibility of research results and are unacceptable.

[1] The term "unique research resource" is used in its broadest sense to embrace the full range of tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines. The terms "research tools" and "materials" are used throughout this document interchangeably with "unique research resources." Databases and materials subject to copyright, such as software, are also research tools in many contexts. Although the information provided here may be applicable to such resources, the NIH recognizes that databases and software present unique questions which cannot be fully explored in this document.

2. *Ensure Appropriate Implementation of the Bayh-Dole Act*

When a Recipient's research work is funded by NIH, the activity is subject to various laws and regulations, including the Bayh-Dole Act (35 U.S.C. 200 *et seq.*). Generally, Recipients are expected to maximize the use of their research findings by making them available to the research community and the public, and through their timely transfer to industry for commercialization.

The right of Recipients to retain title to inventions made with NIH funds comes with the corresponding obligations to promote utilization, commercialization, and public availability of these inventions. The Bayh-Dole Act encourages Recipients to patent and license subject inventions as one means of fulfilling these obligations. However, the use of patents and exclusive licenses is not the only, nor in some cases the most appropriate, means of implementing the Act. Where the subject invention is useful primarily as a research tool, inappropriate licensing practices are likely to thwart rather than promote utilization, commercialization and public availability of the invention.

In determining an intellectual property strategy for an NIH-funded invention useful primarily as a research tool, Recipients should analyze whether further research, development and private investment are needed to realize this primary usefulness. If it is not, the goals of the Act can be met through publication, deposit in an appropriate databank or repository, widespread non-exclusive licensing or any other number of dissemination techniques. Restrictive licensing of such an invention, such as to a for-profit sponsor for exclusive internal use, is antithetical to the goals of the Bayh-Dole Act. Where private sector involvement is desirable to assist with maintenance, reproduction, and/or distribution of the tool, or because further research and development are needed to realize the invention's usefulness as a research tool, licenses should be crafted to fit the circumstances, with the goal of ensuring widespread and appropriate distribution of the final tool product. Exclusive licensing of such an invention, such as to a distributor that will sell the tool or to a company that will invest in the development of a tool from the nascent invention, can be consistent with the goals of the Bayh-Dole Act.

3. *Minimize Administrative Impediments to Academic Research*

Each iteration in a negotiation over the terms of a license agreement or materials transfer agreement delays the moment when a research tool may be put to use in the laboratory. Recipients should take every reasonable step to streamline the process of transferring their own research tools freely to other academic research institutions using either no formal agreement, a cover letter, the Simple Letter Agreement of the Uniform Biological Materials Transfer Agreement (UBMTA), or the UBMTA itself. The Appendix of the Principles and Guidelines contains an updated free-standing version of the Simple Letter Agreement that is strongly encouraged for transfers of unpatented research materials among Recipients.

Where they have not already done so, Recipients should develop and implement clear policies which articulate acceptable conditions for acquiring resources, and refuse to yield on unacceptable conditions. NIH acknowledges the concern of some for-profit organizations that the concept of purely academic research may be diluted by the close ties of some not-for-profit organizations with for-profit entities, such as research sponsors and spin-off companies in which such organizations take equity. Of concern to would-be providers is the loss of control over a proprietary research tool that, once shared with a not-for-profit Recipient for academic research, results in commercialization gains to the providers' for-profit competitors. Recipients must be sensitive to this legitimate concern if for-profit organizations are expected to share tools freely.

For-profit organizations, in turn, must minimize the encumbrances they seek to impose upon not-for-profit organizations for the academic use of their tools. Reach-through royalty or product rights, unreasonable restraints on publication and academic freedom, and improper valuation of tools impede the scientific process whether imposed by a not-for-profit or for-profit provider of research tools. While these Principles are directly applicable only to recipients of NIH funding, it is hoped that other not-for-profit and for-profit organizations will adopt similar policies and refrain from seeking unreasonable restrictions or conditions when sharing materials.

EXHIBIT K

REDACTED IN ITS ENTIRETY

EXHIBIT L

REDACTED IN ITS ENTIRETY

EXHIBIT M

REDACTED IN ITS ENTIRETY

EXHIBIT N

REDACTED IN ITS ENTIRETY

EXHIBIT O

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EXHIBIT P

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EXHIBIT Q

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EXHIBIT R

REDACTED IN ITS ENTIRETY

EXHIBIT S

REDACTED IN ITS ENTIRETY

EXHIBIT T

REDACTED IN ITS ENTIRETY

EXHIBIT U

REDACTED IN ITS ENTIRETY

EXHIBIT V

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the restriction on the cover sheet of this proposal or quotation

EXHIBIT A

MATERIALS TRANSFER AGREEMENT

This Agreement is entered into between the National Institute of Allergy and Infectious Diseases ("NIAID"), an institute of the National Institutes of Health ("NIH"), which is part of the U.S. Public Health Service ("PHS") and the Department of Health and Human Services ("DHHS"), an agency of the U.S. Government, having an address at 31 Center Drive, Room 3B62, Bethesda, Maryland 20892, U.S.A. and Acambis, Inc. ("Recipient"), a corporation of Delaware, having an office at 38 Sidney Street, Cambridge, MA 02139.

1. Definitions:

   a. "Materials" means the following biological materials: Modified Vaccinia Ankara (MVA) virus 572.FHE-22.02.1974, as described in Mayr et al., Passage history, properties and applicability of the attenuated vaccinia virus strain MVA, *Infection* 3: 6-14 (1975) and which was plaque purified by Dr. Bernard Moss of the NIAID.

   b. "Commercial Products" means a Modified Vaccinia Ankara (MVA) Vaccine, which includes Materials or its derivatives.

2. Recipient wishes to use the Materials provided under this Agreement in its internal commercial research, product development and marketing of Commercial Products. Recipient represents that it has the facilities, personnel, and expertise to use the Materials for such commercial purposes and agrees to expend reasonable efforts and resources to develop Commercial Products in a timely manner using the Materials.

3. NIAID hereby grants to Recipient worldwide, non-exclusive rights to make, have made, and use the Materials and to make and have made, to use and have used, to sell and have sold, and to offer to sell Commercial Products in the Field of Use of Smallpox Vaccines.

4. To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of NIAID's written information about the Materials that is stamped "CONFIDENTIAL," except for information that was previously known to Recipient or that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Any oral disclosures from NIAID to Recipient shall be identified as being CONFIDENTIAL by notice delivered to Recipient within ten (10) days after the date of the oral disclosure. Recipient may publish or otherwise publicly disclose the results of its research activities with the Materials, but if NIAID has given CONFIDENTIAL information to Recipient such public disclosure may be made only after NIAID has had thirty (30) days to review the proposed disclosure to determine if it includes any CONFIDENTIAL information, except when a shortened time period under court order pertains.

5. Recipient agrees to provide a written report to NIAID within sixty (60) days after the end of each calendar year during the term of this Agreement. This report shall document the progress made towards producing a smallpox vaccine and list all activities and results obtained using the Materials during the preceding calendar year. Recipient shall submit these reports to NIAID at the Mailing Address for Notices indicated on the Signature Page of this Agreement.

6. Recipient agrees to provide, at no charge, the laboratory of Dr. Bernard Moss at NIAID reasonable quantities of Materials and Commercial Products that Recipient makes, uses, sells, or offers for sale or otherwise makes available for public use under terms no more restrictive than those of the NIH Simple Letter Agreement (Federal Register [64 FR 72090]) (Attached).

7. Recipient agrees to retain control over the Materials, and not to distribute them to third parties without the prior written consent of NIAID except as permitted in Paragraph 3.

8. Recipient agrees that this Agreement does not preclude NIAID from distributing the Materials to third parties for research or commercial purposes.

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the restriction on the cover sheet of this proposal or quotation

9. By this Agreement, NIAID grants no patent rights expressly or by implication to any anticipated or pending NIAID patent applications or issued patents.

10. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE MATERIALS PROVIDED TO RECIPIENT UNDER THIS AGREEMENT, OR THAT THE MATERIALS OR COMMERCIAL PRODUCTS MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. Recipient accepts transfer of the Materials "as is", and NIAID does not offer any guarantee of any kind.

11. Recipient agrees to indemnify and hold harmless the United States Government from any claims, costs, damages, or losses that may arise from or through Recipient's use of the Materials or Commercial Products. Recipient further agrees that it will not by its action bring the United States Government into any lawsuit involving the Materials or Commercial Products.

12. Recipient agrees in its use of Materials to comply with all applicable statutes, regulations, and guidelines, including PHS and DHHS regulations and guidelines. Recipient agrees not to use the Materials or the Commercial Products for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. Recipient agrees not to use the Materials or Commercial Products for research involving human subjects or clinical trials outside of the United States without notifying NIAID, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to NIAID of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.

13. Recipient may terminate this Agreement upon sixty (60) days written notice to NIAID.

14. NIAID may terminate this Agreement if Recipient is in default in the performance of any material obligation under this Agreement, and if the default has not been remedied within ninety (90) days after the date of written notice by NIAID of such default.

15. Upon termination of this Agreement, Recipient agrees to return all Materials and Commercial Products to NIAID, or provide NIAID with certification of their destruction.

16. Within ninety (90) days of termination of this Agreement, Recipient agrees to submit a final report to NIAI, that specifies all activities and results related to use of Materials and Commercial Products by Recipient.

17. This Agreement shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this Agreement. Recipient agrees to be subject to the jurisdiction of U.S. courts.

18. This Agreement constitutes the entire understanding of NIAID and Recipient and supersedes all prior agreements and understandings with respect to the Materials.

19. This Agreement shall become effective on the date when the last party has signed this Agreement .

20. The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions of this Agreement.

21. Paragraphs 4, 10, 11, 12, 15, 17, 18, 20, and 21 shall survive termination of this Agreement.

SIGNATURES BEGIN ON NEXT PAGE

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the restriction on the cover sheet of this proposal or quotation

NIAID BIOLOGICAL MATERIALS TRANSFER AGREEMENT

SIGNATURE PAGE

In Witness Whereof, the parties have executed this Agreement on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For NIAID:

/Michael R. Mowatt/ 11 SEP 2002

Michael R. Mowatt, Ph.D. Date
Director, Office of Technology Development

Mailing Address for Notices: OFFICE OF TECHNOLOGY DEVELOPMENT
NIAID, NIH
Building 31 Room 3B62
Bethesda MD 20892-2137

Tel: 301/496-2644 Fax: 301/402-7123

For Recipient (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of Recipient made or referred to in this document are truthful and accurate.):

By: 9/10/02

Stephen H. Atkinson Date
Vice President, Commercial Development

Stephen H. Atkinson
Printed Name

Mailing Address for Notices: Acambis, Inc.
38 Sidney Street
Cambridge, MA 02139

Any false or misleading statements made, presented, or submitted to the U.S. Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment).

EXHIBIT W

REDACTED IN ITS ENTIRETY

EXHIBIT X

FW: Anton Mayr asks Peter to call him !!

as ht PW

THERION
BIOLOGICS

February 26, 2002

Prof.Dr.Dr.h.c.mult. Anton Mayr
Institute for Medical Microbiology and Infectious Diseases
Veterinary Faculty of the University of Munich
Veterinärstraße 13
Munich 80539
GERMANY

Dear Professor Dr. Mayr,

It was a pleasure to speak with you today.

As per our telephone conversation, I am writing about the MVA virus, MVA 572.CEF v.22.2.74, that you sent to Dr. Bernard Moss. Dr. Moss is willing to send us the virus but would like written permission from you before he sends us the virus.

Therefore I would greatly appreciate it if you would send such a letter, giving Dr. Moss permission to provide MVA 572.CEF v.22.2.74 (and derivatives) to Therion, at your earliest convenience:

Dr. Bernard Moss
Laboratory of Viral Diseases
DIR, NIAID, NIH
Building 4, Room 229
4 Center Drive
MSC 0445
Bethesda, MD 20892-0445
USA

Please send a copy of the letter to:

Linda Gritz, Ph.D.
Therion Biologics Corporation
76 Rogers St
Cambridge, MA 02142
USA

Thank you very much.

Sincerely,

Linda Gritz, Ph.D.
Principal Scientist

Therion Biologics Corporation
76 Rogers Street Cambridge, Massachusetts 02142
Phone (617) 876-7779
Fax (617) 876-9391

EXHIBIT Y

Prof. Dr. Dr. h.c.mult. Anton Mayr
Inst. For Medical Microbiology and Infectious Diseases
Veterinary Faculty University Munich
Veterinaerstrasse 13
Munich 80539
Germany

cc: PW
PCH
MMR
305
PPI

Dr. Bernard Moss
Laboratory of Viral Diseases
DIR. NIAID. NIH
Building 4. Room 229
4 Center Drive
MSC 0445
Bethesda, MD 20892-0445
USA

Beforehand by fax: (301) 4801 147

6th November 2002

Ref. MVA and uses thereof

Dear Dr Moss

I am writing to enquire about recent events that have come to my attention regarding the commercialization by the NIH of MVA as a safe smallpox vaccine. Under the recent RFP (NIH-NIAID-DMID-03-44) it states that the NIH is willing to provide successful applicants a MSV of MVA for the development of a smallpox vaccine and I have recently discovered that the NIH is funding a Phase I clinical program. I assume from the recent reports of your involvement with Dr Jahrling (USAMRIID) for the purposes of performing a primate monkey pox study that this source of MVA has been provided by yourself, derived from the various stocks of MVA which I have provided to you in the past.

I am a little surprised by these events as I have provided MVA to academic partners for research purposes only. You initially received MVA from the time Dr Sutter (Postdoctoral Fellow working for me) visited your laboratory through a German grant that I was awarded during 1990. Upon your request for other sources of MVA for 'expression vector work' I provided MVA 575 and MVA II/85 in 1995 and MVA 572 during 2001. I have always been willing to collaborate with you in the past, but MVA was only ever provided to support your academic research at the NIH. From recent letters I have received from Therion (Jan & Feb 2002) requesting my permission to allow you to provide them MVA 572. I thought you fully understood that the MVA I provided was for academic research purposes only.

BN ITC 50318909

Several MVA strains, including MVA 572, were deposited by myself in the European tissue culture collection which prohibits the commercialization of the deposited strain, or their derivatives. without the written permission from the organization, or individual that deposited the virus. Furthermore, I have provided an exclusive license for the commercialization of all MVA strains to Bavarian Nordic and therefore your disregard for our long-standing collaboration has put me in a compromised position with the company I have been working with since 1997. I am also disappointed as MVA represents a significant achievement in my scientific career and while I am happy to see people working with my invention I am disappointed to think that I would not be recognized for my achievements should MVA be commercialized by the NIH, or by other companies that have received sources of MVA strictly meant for research purposes.

I would appreciate an update of your activities using any of the MVA strains, or their derivates that I have provided to you over the years.

Yours sincerely

Dr. Anton Mayr

Prof. Dr. Dr. h.c. mult. Anton Mayr
Lehrstuhl für Mikrobiologie
und Seuchenlehre
Veterinärstraße 13
80539 München

Prof. Dr. Dr.h.c.mult. Anton Mayr

EXHIBIT Z

REDACTED IN ITS ENTIRETY